scientists continue to have questions about a possible association and CDC is currently conducting a more detailed study of thimerosal-containing vaccines and autism.

Can vaccines "overload" my child's immune system?

The number of vaccines given to children has increased from 5 forty years ago to 11 today. A fully vaccinated child will receive as many as 20 separate shots by their second birthday (see the childhood and adolescent vaccine schedule recommended by CDC at http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm.) It's no wonder that many parents worry their child's immune system will be overwhelmed by having to handle so many vaccines. However, an infant's immune system is designed to respond to a very large number of antigens (foreign proteins that cause an immune system response), and babies are constantly exposed to new antigens from the moment they're born in the food they eat and the air they breathe. For instance, if all 11 vaccines were given to an infant at once, only about 0.1% (one tenth of one percent) of their immune system would be "used up".[19] Put another way, it would take 10,000 vaccines given at the same time before a child's immune system would be overwhelmed. See reference number 19 in the Sources that are listed below for a medical journal article that describes how scientists came up with these numbers.

Another point to consider is that, even though children receive more shots today, the number of antigens in those shots has actually gone down over the years. When children received the smallpox vaccine, they were exposed to about 200 different proteins. Now that children no longer need smallpox vaccine, they receive less than 130 proteins from all 11 recommended vaccines combined. The number of proteins has also been reduced because of better technology in vaccine production.[19]

Would my child get a disease if not vaccinated?

He may or may not. If an unvaccinated child were exposed to the disease, there is a good chance he would get the disease. However, if your child is not exposed, due in large part to "community immunity," he would not get the disease. If enough people in the community are immunized against certain diseases, then it is more difficult for that disease to get passed from person to person. Community immunity also protects people who are too sick or too young to receive the vaccine, or people who have received a vaccine that didn't produce an immune system response.

Sources

1. Offit PA & Jew RK. Addressing parents' concerns: Do vaccines contain harmful preservatives, adjuvants, additives, or residuals? Pediatrics. 2003; 112(6): 1394-1401.
2. Feikin, DR et al. Individual and community risks of measles and pertussis associated with personal exemptions to immunization. JAMA. 2000; 284:3145-3150.
3. Offit, P; Bell, LM. Vaccines: What you should know. Third edition, 2003
4. Offit, PA & Hackett CJ. Addressing parents' concerns: Do vaccines cause allergic or autoimmune diseases? Pediatrics. 2003; 111(3):653-659
5. http://www.cdc.gov/od/science/iso/concerns/gbsfactsheet.htm
6. http://www.cdc.gov/vaccines/vac-gen/side-effects.htm
7. Wakefield, A.J. et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. The Lancet. 1998; 351:637-641
8. Taylor B, et al. Measles, mumps, and rubella vaccination and bowel problems or developmental regression in children with autism: population study. BMJ. 2002 Feb 16; 324(7334):393-6
9. Madsen KM, et al. A population-based study of measles, mumps, and rubella vaccination and autism. N Engl J Med. 2002 Nov 7; 347(19):1477-82
10. Fombonne E & Chakrabarti S. No evidence for a new variant of measles-mumps-rubella-induced autism. Pediatrics. 2001 Oct; 108(4):E58
11. Taylor, B et al. Autism and measles, mumps, and rubella vaccine: no epidemiological evidence for a causal association. The Lancet. 1999; 353:2026-2029
12. Murch SH et al. Retraction of an interpretation. The Lancet. 2004; 363:750
13. www.iom.edu/about.asp
14. http://www.iom.edu/project.asp?id=4705
15. www.vaccinesafety.edu
16. Verstraeten T, et al. Safety of thimerosal-containing vaccines: A two-phased study of computerized health maintenance organization databases. Pediatrics. 2003; 112:1039-1048.
17. Andrews N, et al. Thimerosal exposure in infants and developmental disorders: A restrospective cohort study in the United Kingdom does not support a causal association. Pediatrics. 2004; 114:584-591.
18. Madsen KM et al. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. Pediatrics. 2003; 112:604-605
19. Offit PA, et al. Addressing parents' concerns: Do vaccines weaken or overwhelm the infant's immune system? Pediatrics. 2002; 109:124-129

Paying for vaccines

If your child does not have health insurance, or is only partly insured, ask your doctor or local health department about getting help to pay for vaccines.

Please be fully informed

We at the Michigan Department of Community Health think that vaccines are important to the health of your child. We want you to be an informed partner in the decision to vaccinate your child. For more information, please see the references mentioned throughout this brochure. Contact your local library if you need help finding the medical journal articles. You can also visit the internet sites listed throughout the brochure.

For more information:

www.vaccinesafety.edu

www.chop.edu/consumer/your_child/index.jsp

www.immunize.org

www.cdc.gov/vaccines

www.consumerreports.org
(search for "vaccine safety")

More questions? Call:

- Your health care provider
- Your local health department
- Visit: www.michigan.gov/immunize

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CHILDHOOD IMMUNIZATIONS: VACCINE SAFETY

Why Vaccinate your Child?

Should I vaccinate my child?

Because most vaccine preventable diseases are so uncommon in the United States, it can be hard to understand why we need to keep vaccinating our children. In addition, it seems every few months the news media is reporting that vaccines can cause serious side effects. Parents like you want to protect your children from harm, but without all the information it can be hard to decide whether or not to have your child vaccinated. We at the Michigan Department of Community Health believe children should be vaccinated. Here's why: 1) these diseases still exist in the world, and your child could come in contact with them through people moving to your community or people who have traveled to other parts of the world, 2) these diseases can cause severe illness in some children, and 3) if infected with a disease, your child could pass it on to others, which could cause them serious illness as well. We understand that you may have questions about the safety of vaccines for your child. This brochure will provide you with answers to some common questions, as well as books, medical journals, and websites where you can find more information.

What is in a vaccine?

Vaccines are made with actual disease bacteria or viruses that are either killed or weakened. Vaccines produce long-lasting immunity from disease without making your child sick. Vaccines work the same way as a natural infection. The body reacts to viruses or bacteria in vaccines by making antibodies. An antibody is a special kind of protein made by white blood cells that fights infections. Antibodies are disease specific, so a child who has a polio vaccination, but not a chickenpox vaccination, has antibodies to fight polio, but not chickenpox. The body will use these antibodies to fight off the disease if it ever enters the body again.

Vaccines also contain other ingredients, called additives. These additives are there to keep vaccine ingredients stable from changes in temperature or environment.[1] These additives are safe, although very rarely they can cause serious allergic reactions in some people. Different vaccines contain different additives. For detailed information on the additives in each vaccine, ask your doctor or pharmacist for a list of the ingredients found in the vaccine package materials. You can also find most of these "package inserts" online at: http://www.vaccinesafety.edu/package_inserts.htm.

Do children still get these diseases?

Yes. Since these diseases still occur in other parts of the world, and because the world becomes smaller each day due to international travel, vaccine preventable diseases can be spread due to people traveling or moving to your community. A recent study in Colorado showed that unvaccinated kids were 22 times more likely to get measles and 6 times more likely to get whooping cough than vaccinated kids.[2]

Are these diseases really serious?

Yes, for some children the diseases can be very severe. Chickenpox, measles and whooping cough can cause serious harm like deafness, brain damage, and even death. In 1990-1991 in Philadelphia, a measles outbreak resulted in over 1,500 cases and nine deaths when vaccination coverage in the city decreased.[3]

How are vaccines tested?

Vaccines go through three phases (levels) of testing in people before they are licensed for nationwide distribution. Studies in people take place only after the vaccine has been tested in a laboratory and then tested in animals. Animals are used because their immune system is similar to people. Tests on animals help predict the effect on people. Each test phase is reviewed by the Food and Drug Administration (FDA) to make sure that every vaccine is safe and effective. The three phases are briefly described below. The people receiving the vaccine are closely monitored for their safety during all three test phases.

After the series of studies is complete,

FDA scientists must review and approve the: 1) study results, 2) package insert materials, and 3) manufacturing plans. FDA may then conduct more tests of the vaccine in its laboratories. Next, FDA inspectors make sure that the manufacturing plant is able to produce the vaccine properly. All of this is done before the vaccine is licensed for the public. This license covers both the vaccine and the manufacturing plant. When the vaccine is in production, the FDA requires the company to test samples from each lot (batch) for safety, potency, and purity. FDA also carries out its own spot testing. The entire process – from reviewing the study results to FDA spot testing – is required for all companies that make vaccines. For more on what happens after the vaccine studies, visit the FDA website at http://www.fda.gov/opacom/factsheets/justthefacts/19vaccine.html

Post licensure safety The Vaccine Adverse Event Reporting System (VAERS) monitors vaccine safety after the vaccine is licensed by the FDA. VAERS receives reports on side effects following vaccinations. The VAERS employees at the FDA and the CDC use the information to make sure known side effects do not increase and new or very rare side effects are detected. Drug companies that manufacture vaccines also conduct ongoing studies to assess the effectiveness of vaccines. These studies are required as part of the vaccine's license.

For more information on vaccine testing and licensure, see the FDA's website at: www.fda.gov/cber/vaccine/vacappr.htm

Phase 1 ***Immune response studies*** Vaccines that are proven safe in animals are then tested with a small number of volunteers (usually 10 to 100 people). The focus of this phase is to understand how peoples' immune systems respond to the vaccine. A person's immune response is measured by testing their blood to see if there are any antibodies that formed in response to a dose of a new vaccine.

Phase 2 ***Dosage studies*** This testing is usually done with hundreds of volunteers. The people involved receive different amounts of the vaccine to help determine: 1) the most effective use of the vaccines 2) the best dose for effectiveness and safety 3) the right number of doses, and 4) common adverse reactions recorded.

Phase 3 ***Large studies*** This last phase of testing usually involves thousands of volunteers and may last several years. During this phase the people's blood is drawn at different times after they receive the vaccination. The amount of antibodies in the blood is measured to determine how effective the vaccine is at protecting the body from disease. Some volunteers receive another licensed vaccine instead of the vaccine under study so it can be compared for effectiveness and for adverse reactions.

For more information on the VAERS surveillance system which is co-managed by the FDA and the CDC, see the VAERS website at http://vaers.hhs.gov.

Are there long-term effects of vaccines?

Some parents are concerned that vaccines can cause long-term autoimmune disorders, such as asthma, multiple sclerosis, or diabetes. Well-designed epidemiologic studies have shown no relationship between these chronic diseases and vaccines.[4] It is true that there have been examples of vaccines causing serious health problems. For example, the oral polio vaccine, which is no longer used in the U.S., very rarely caused polio. In 1976, the flu vaccine was associated with an increase in Guillain-Barre syndrome.[5] Also, in rare circumstances, vaccines have caused serious side effects like seizures and allergic reactions. It's important to consider both the risks and benefits when making decisions about vaccines for your child. It is true that, as with any medicine, there are risks of side effects from vaccines. However, most of these side effects are mild, and only very rarely are they life-threatening.[6]

What about autism?

In 1998, British doctors published a report of a group of eight children who had developed autism after receiving the measles-mumps-rubella (MMR) vaccine.[7] They proposed that the vaccine had caused the children's intestines to leak toxins into the bloodstream. The toxins then may have damaged brain tissue, causing autism. This theory has been questioned in later studies.[8-11] Other scientists have not been able to find evidence that MMR vaccine may cause autism. In February 2004, 10 of the 1998 study's 13 co-authors withdrew their original interpretation of the data.[12]

The Institute of Medicine (IOM) is an independent, non-profit organization that reviews important health topics for the U.S. government.[13] In 2001, and again in 2004, the IOM reviewed the scientific evidence regarding MMR vaccine and autism.[14] In 2001, they concluded that scientific evidence showed no link between MMR vaccine and autism in the general population. They also concluded that they could not yet rule out the possibility that MMR vaccine contributed to autism in a small subset of children, because not enough studies had been done on that specific topic. The report called for more research to be done. In 2004, after reviewing more studies, they concluded that: "the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism."[14] For more information on this topic, see the John Hopkins University website, referenced below under the topic "MMR"[15], the CDC website at: http://www.cdc.gov/od/science/iso/concerns/mmr_autism_factsheet.htm, or the Vaccine Center at the Children's Hospital of Philadelphia website at www.chop.edu/consumer/your_child/index.jsp. You can also read both the 2001 and 2004 IOM reports on MMR vaccine and autism at: http://www.iom.edu/project.asp?id=4705.

What about mercury in vaccines?

Mercury is a common metal that is found throughout the environment in different forms (for example, methyl mercury is an environmental contaminant found in fish). Thimerosal, which contains 49% ethyl mercury, was used as a preservative in some vaccines from the 1930s until 1999. In June of 1999, the FDA announced that infants who received several thimerosal-containing vaccines in the first few months of life could be exposed to mercury levels that are higher than recommended. In July of 1999, the Public Health Service and the American Academy of Pediatrics recommended that thimerosal be taken out of vaccines as a precautionary measure and to reduce overall mercury exposure in children. Thimerosal has been removed from all vaccines, except for some types of flu vaccine. Even though it is still present in trace amounts in some vaccines, these trace amounts are too small to have any biologic effect. For a list of which vaccines used to contain thimerosal, and when thimerosal was removed from each vaccine, visit the FDA website at: http://www.fda.gov/cber/vaccine/thimerosal.htm.

It has been suggested that mercury in vaccines may have caused autism in some children. Several scientific studies have been unable to prove this link.[16,17] For example, thimerosal was removed from childhood vaccines in Denmark 10 years ago, yet autism cases have continued to rise there.[18] In 2004, the Institute of Medicine (IOM), an independent, nonprofit organization that reviews important health topics for the U.S. government, reviewed the evidence on this issue. The IOM concluded that there is no association between autism and thimerosal-containing vaccines.[14] Nonetheless, some parents and